K120628

510(K) Summary

DEC 19 2012

Submitter
Motion Composites
519 J-Oswald-Forest Suite 101
Saint-Roch-de-l'Achigan, QC, Canada
J0K 3H0

Telephone : (450)588-6555
Fax : (450) 588-0200

Contact : M. Vincent Lécuyer

Trade Name : Helio
Classification Name : Mechanical wheelchair
Classification : Class I

Indications For Use:

The helio wheelchair is a manually operated device intended to be used as a means of mobility for persons restricted to a sitting position. It is not indicated for the pediatric population.

Predicate Devices :

The first predicate device is the Quickie 2 wheelchair for the overall safety and effectiveness of the product :
510(K) number K850536

The second predicate device is the Quickie carbon wheelchair for the safety and effectiveness of carbon fiber as the main material for frame and crossbrace in a mechanical wheelchair :
510(K) number K915533

Device Description

The helio is a traditional folding cross-brace wheelchair. It is made of lightweight hi-Modulus carbon fiber mixed with epoxy resin similar to what is used on existing products such as **K915533**. The frame

utilizes one patented cross brace system that, when opened, nestles inside of the frame onto 4 hooks to create a box like rigid assembly. Upon the outside of this framework, and to the rear, are assembled two aluminum axle plates. Wheels of varying size and type are connected to the stainless steel axle receivers via stainless steel axles.

On the front end of the frame are assembled 2 aluminum caster housings. Caster forks are mounted to these housings via stainless steel axles. A variety of caster wheels and tires are then connected to the forks. Upon the top of the frame is attached a seat sling. Into the rear of the frame assembly 2 back tubes are inserted to the desired height. Backrest upholstery is affixed to the back tubes. Armrests receivers bolt onto the rear of each side frame. Individual swing away armrests are then inserted into the receivers. If flip back armrests are chosen, a receiver is mounted onto the front of each side frame to catch the forward most section of the arm and the rear mounting is pivoting to allow the arm to rotate backward. Height Adjustable arms fit into a receiver that mounts onto the outside of the frame.

Wheel locks mount onto the upper side frame and are adjusted so that the brake arm engages with the tire and when in the locked position prevents to the wheel from rotating. Footrests with footplates attach at the front of the chair. There is a plug at the top of the footrest hanger that inserts into an opening at the top front of the wheelchair frame. The footrest hanger is inserted 90 degrees away from the frame and rotates inwards. The latch will engage once the footrest hanger is centered.

	Description	Materials
Intended Use	The helio wheelchair is a manually operated device intended to be used as a means of mobility for persons restricted to a sitting position	
Primary Frame Materials	Composite Materials	Hi Modulus carbon fiber + epoxy resin
Folding Method	Collapsible Cross-Brace	Hi Modulus carbon fiber + epoxy resin
Frame Widths	12" to 20"	
Overall Width	19 1/2" to 27 ½"	
Seat Depths	12" to 20"	
Back Heights	9" to 21"	
Weight Limit	220 lbs	
Seat H ight	13 1/2" to 22 1/4"	
Chair Weight	14.5 lbs (without footrests)	
Warranty	Limited Lifetime on frame	
Armrests	Flip back Height adjustable T-Shaped Armrests - Height adjustable Tubular Swing-away	6061-T6 Aluminum + Plastic + Pu foam
Front End Type	Swing-Away Fixed Front Frame	6061-T6 Aluminum
Back Type	Straight 8 degree bend back Adjustable angle- straight or 8 degree bend	Hi Modulus carbon fiber + epoxy resin OR 6061-T6 Aluminum
Footrests Hangers	60, 70 and 90 degrees hangers	6061-T6 Aluminum
Footplates	Composites Angle Adjustable Oversized one-piece flip-up	Plastic, 6061-T6 Aluminum
Extension Tubes	Short, Medium, Long	6061-T6 Aluminum
Back upholstery	Slip on back	Nylon #420 black
	Adjustable tension back	Nylon #840 & #210 black
Seat Upholstery	Nylon seat sling	Fire resistant Sailcloth
Cushion	2" or 3" foam cushion	1" FOAM B4130
Axle Plates		6061-T6 Aluminum
Wheel sizes	20 ,22,24, 25" 26 "	
	Plastic Mags	Plastic + 6061-T6 aluminum hub
	Regular Spoke	Aluminum Rim, Stainless spoke and Aluminum hub
Wheel Types	Spinergy Wire	Aluminum Rim, Stainless spoke and Aluminum hub
	Spinergy LX	Aluminum Rim, PBO spoke and Aluminum hub
	Spinergy Spox	Aluminum Rim, PBO spoke and Aluminum hub
Tire Types	Pneumatic regular and high pressure Full and low profile polyurethane Hard Urethane	Synthetic rubber and urethane
Handrims	Aluminum Anodized Plastic Coated (regular or high friction) Spinergy Flexrim Natural Fit handrim	
Caster Sizes	3" to 8"	
Caster types	Composites wheel	Polyurethane tires
	Pneumatic	Synthetic rubber and urethane
Fork Sizes	3",4",5", 7"	6061-T6 Aluminum
Fork Stem Sizes	std, +1 , +2	HT4140 Steel
Wheel Locks	Push to lock, pull to lock, Scissor brake	6061-T6 Aluminum
Anti tips tubes	Short, Medium, Long	6061-T6 Aluminum
Target Population	Persons restricted to a sitting position	
Standards	ISO 7176 1,5,8,11,15	
Tubing wall thicknesses	1/16"	
Tube Properties	Strong enough to pass ISO7176 double cycle (400 000)	

Technological comparison to the predicate device

DEVICES	Quickie Wheelchair (K850536)	Quickie Carbon (K915533)	Helio wheelchair
Intended Use	The Quickie Wheelchair is a manually operated device intended to be used as a means of mobility for persons restrict to a sitting position.	The Quickie Carbon is a manually operated device intended to be used as a means of mobility for persons restrict to a sitting position.	The helio wheelchair is a manually operated device intended to be used as a means of mobility for persons restrict to a sitting position.
Primary Materials*	Aluminum 6000 series	Hi-Modulus Carbon Fiber	HI-Modulus Carbon fiber + Epoxy Resin
Folding Method	Collapsible Cross-Brace	Fixed Frame	Collapsible Cross-brace
Frame Width	11" to 22"	14" to 20"	12 " to 20"
Overall width	20,5" to 28,5"	20,5" to 28,5"	19 ½ to 31 ½"
Seat Depth	10" to 20"	14" to 20"	12" to 20"
Back Heights	8,5" to 19"	8,5" to 19"	9" to 21"
Weight Limit :	250lbs	250lbs	220 lbs
Seat height :	16.75" to 22.75".	16.75" to 22.75".	13 ½" to 22 ¼"
Chair Weight (without footrests)	27 lbs	unknown	14.5 lbs
Warranty	Lifetime on frame	Lifetime on frame	Lifetime on frame
Armrests	Flip back Height adjustable T-Shaped Armrests - Height adjustable Tubular Swing-away	Flip back Height adjustable T-Shaped Armrests - Height adjustable Tubular Swing-away	Flip back Height adjustable T-Shaped Armrests - Height adjustable Tubular Swing-away
Front end types	Swing-Away Non swing-away	Swing-Away Non swing-away	Swing-Away Non swing-away
Back Type	Standard Angle Adjustable Depth Adjustable Standard	Standard Angle Adjustable	Standard Angle Adjustable
Footrest Hangers	60,70,90 degrees, elevating legrests	60,70,90 degrees	60,70,90 degrees, elevating legrests
Footplates	Composites, Foam, Aluminum angle adjustable	Composites, Foam, Aluminum angle adjustable	Composites, Aluminum angle adjustable, one piece flip-up
Back Upholstery	Low, Medium, Tall, Adjustable,	Low, Medium, Tall, Adjustable,	Standard, Adjustable
Axle Plates	Standard, Curved, Amputee, Offset Standard	Standard, Curved, Amputee, Offset Standard	Standard, Amputee
Wheel sizes	20,22,25,26 "	20,22,25,26 "	20,22,24,26 "
Wheel types	Spoke, Composite Mag, Spinergy, One arm drive	Spoke, Composite Mag, Spinergy, One arm drive	Spoke, Composite Mag, Spinergy Wire, LX and Spox
Tire types	Pneumatic, Pneumatic w/ airless Insert Polyurethane, Low Profile Full profile Iron Cap	Pneumatic, Pneumatic w/ airless insert, Polyurethane, Low Profile Full profile , Iron Cap	Pneumatic regular and high pressure Full and low profile polyurethane Hard Urethane
Handrims	Aluminum, Plastic Coated, Projections	Aluminum, Plastic Coated, Projections	Aluminum, Plastic coated, high friction, Natural Fit
Caster Sizes	4",5",6",8"	4",5",6",8"	3" to 8"
Caster types	Polyurethane, semi-pneumatic, Soft Roll, Pneumatic	Polyurethane, semi-pneumatic, Soft Roll, Pneumatic	Composites wheels, Pneumatic, Soft Roll
Fork Sizes	3",4",5",6",7"	3",4",5",6",7"	3",4",5",7"
Fork Stem Sizes	Std,+3/4",+1 ½"	Std,+3/4",+1 ½"	std, +1 , +2
Caster Options	Multi-position fork caster, pin locks	Multi-position fork caster, pin locks	Multi-position fort caster, pin locks
Wheel Locks	Push to lock, pull to lock, scissor lock	Push to lock, pull to lock, scissor lock	Push to lock, pull to lock, scissor lock
Anti-tip tubes	Yes	Yes	Yes
Target population	Restricted to a sitting position	Restricted to a sitting position	Restricted to a sitting position
Standards	Unknown	Unknown	ISo 7176 part 1, 5, 8, 11, 15.

It is Motion Composites' conclusion that the helio manual wheelchair is substantially equivalent to the Quickie 2 manual wheelchair (K850536) and the Quickie carbon (K915533) .

Summary of Performance Testing

The helio has been tested and found to comply with these recognized international standards :

- *16-158 ISO 7176-1 : Wheelchairs, part 1 : Determination of static ability.*
- *16-163 ISO 7176-5 : Wheelchairs, part 5 : Determination of dimensions, mass and manoeuvring space.*
- *ISO 7176-8 : Wheelchairs, part 8 : Requirements and test methods for static, impact and fatigue strengths.*
- *16-24 ISO 7176-11 : Wheelchairs, part 11 : Test dummies.*
- *16-27 ISO 7176-15 : Wheelchairs, part 15 : Requirements for information disclosure, documentation and labeling*

Conclusion

As stated above, Motion Composites' conclusion is that the helio wheelchair is safe, effective, complies with the appropriate medical device standards, and is substantially equivalent to the Quickie 2 and Quickie carbon wheelchair. This 510(k) Summary of Safety and Effectiveness may be copied and submitted to interested parties as required by 21CFR807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 19, 2012

Motion Composites
% Mr. Vincent Lecuyer
Marketing Manager
519 J-Oswald-Forest, Suite 101
Saint-Roch-de-L'Achigan
QC, Canada JOK 3H0

Re: K120628
Trade/Device Name: Helio ultra-light wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: November 19, 2012
Received: November 28, 2012

Dear Mr. Lecuyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -A

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120628

Device Name: Helio ultra-light wheelchair

Indications For Use:
The helio wheelchair is a manually operated device intended to be used as a means of mobility for persons restricted to a sitting position. It is not indicated for the pediatric population.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Brian D. Pullin -S

Division of Neurological and
Physical Medicine Devices
510(k) Number: K120628